

Remarks/Arguments:

Applicants wish to thank Examiner Ja-Na Hines for the courteous consideration rendered applicant Thomas Hartung and applicants' undersigned representative during an interview at the Patent and Trademark Office on July 9, 2009. Substantively, the prior art rejections were discussed during the interview, including how the cited references are patentably distinguishable from the presently claimed invention—which discussions are further detailed below, in the context of the rejections under §102 and §103. It is applicants understanding that the instant, after final claim amendments (further discussed below), which better define patentably distinguishing features of the invention, will be considered by the examiner.

Claims 23-40 are pending, with claims 23 and 35 being independent. Claims 24-34 are dependent (directly or indirectly) on claim 23, and claims 36-40 are dependent (directly or indirectly) on claim 35.

Claims 1-22 are cancelled, without prejudice or disclaimer.

Claims 23 and 25 are amended in order to more clearly define the instant invention by rewriting "blood products" to read "blood product including viable cells," as inherently described throughout the originally filed specification and claims. For example, the originally filed application (page 8) teaches: "After thawing of the deep-frozen blood it is again possible to detect inherent physiological reactions of native immune cells under natural conditions and mixing ratios" (emphasis added).

Claims 23-40 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Reconsideration is requested.

The reason for the alleged failure to comply with § 112, ¶ 2, is that "the substance" recited in claims 23 and 35 allegedly has no antecedent basis. With all due respect, the statement of rejection is incorrect.

The preamble in each of claims 23 and 35 reads "A method of testing blood for reaction to a substance" (emphasis added). Accordingly, the "a substance" recited in the preamble of each of claims 23 and 35 provides the necessary antecedent for "the substance" subsequently recited in each of the claims.

Accordingly, the rejection under § 112, ¶ 2, is overcome and withdrawal of the rejection appears to be in order.

Claims 23-40 were rejected under 35 USC 102(b) as being allegedly anticipated by US 5,364,756 (Livesey). Reconsideration is requested.

As indicated above, the rejection was discussed during the interview, including how the cited reference is patentably distinguishable from the presently claimed invention. As explained during the interview, use of viable blood cells—an inherently recited feature of the rejected claims and an expressly recited feature of the present claims—is absent from each of Livesey and Hill.

Livesey discloses a method in which blood cells are rendered non-viable; whereas the presently claimed invention uses "viable cells." Livesey may start with a biological sample containing live cells, but the Livesey method subjects the cell-containing sample to freeze-drying

(e.g., Livesey: 14, lines 7-44), which results in killing the cells in the sample; which, in fact, is acknowledged in the statement of rejection (Office Action, page 5) ("Livesey et al., teach reconstitution, dehydration where the freezing and drying of biological substances imparts great physical stress upon the bonding forces which normally stabilize macro macular confirmations and a consequence of the procedure includes dissolution of [cell] membrane structure")(emphasis added).

Accordingly, the limitation on the present claims to a "cryopreserved unit dose comprising a blood product including viable cells" (emphasis added)—which "unit dose" is subsequently thawed, contacted with a substance, and tested for any reaction with the substance—is absent from Livesey. The "absence" of the viable cells limitation on the present claims "negates anticipation" of the present claims by Livesey. *Kolster Speed Steel AB v. Crucible Inc.*, 230 USPQ 81, 84 (Fed Cir. 1986). Accordingly, the rejection under §102(b) based on Livesey is overcome and withdrawal of the rejection appears to be in order.

Claims 23-40 were rejected under 35 USC 103 as being allegedly unpatentable over US 4,731,330 (Hill) in view of Livesey. Reconsideration is requested.

The presently claimed method requires the use of "viable cells," which viable cells—present in the frozen/cryopreserved led-product unite dose—are thawed, contacted with a "substance," and tested for any "reaction" with the substance.

On the other hand, neither Hill nor Livesey, taken alone or in combination, teaches or suggests a method that involves determining whether, after freezing and thawing, whether viable

cells react with a substance, in the manner presently claimed. Livesey neither teaches nor suggests such a method, for the reasons set forth above.

As indicated above, the rejection was discussed during the interview, including how the teachings of Hill—alone and in combination with those of Livesey—are patentably distinguishable from the presently claimed invention. As explained during the interview, use of viable blood cells—an inherently recited feature of the rejected claims and an expressly recited feature of the present claims (as indicated above)—is neither taught nor suggested by Hill, alone or in combination with Livesey.

Hill (column 2, lines 48-52) discloses a method of producing a "controlled sample," which "control sample comprises a lyophilized mixture comprising fixed [i.e., dead] red blood cells" (emphasis added). Accordingly, the procedures the "control sample" is subjected to—as disclosed in Hill—it involves the use of dead cells "i.e., not viable cells," as in the present claims.

Again, Livesey neither teaches nor suggests use of viable cells (as explained above). And, as such, Livesey provides no teaching or suggestion that cures the fatal deficiency of Hill—in failure to teach or suggest use of viable cells—as explained above.

Accordingly, taken alone or in combination, the teachings of Hill and Livesey fail to teach or suggest all limitations on the present claims, which is necessary to establish a prima facie case of obviousness under §103(a). *In re Royka*, 180 USPQ 580 (CCPA 1974). Since "the cited references do not support each limitation of [the present] claim[s]," the rejection under §103(a) is "inadequate on its face" against any of the present claims. *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

For the foregoing reasons, the rejection of claims 23-40 under §103(a) based on the combined teachings of Livesey and Hill is overcome. Withdrawal of the rejection appears to be in order.

Favorable action is requested.

Respectfully submitted,



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